Northern, Eastern and Western Devon Clinical Commissioning Group
South Devon and Torbay Clinical Commissioning Group

Clinical Policy Committee (CPC)
Minutes

Wednesday 9th October 2013, 10.00-12 noon

Room C, Tiverton Hospital

Present:

Dr Jo Roberts* (Chair)	GP Clinical Commissioner	South Devon & Torbay CCG
Dr Mick Braddick*	GP Clinical Commissioner	NEW Devon CCG
Rob Cowdry	Contracts Governance Manager, Commissioning	NEW Devon CCG
Dr Andrew Craig*	GP Clinical Commissioner	NEW Devon CCG
Richard Croker*	Head of Medicines Optimisation	NEW Devon CCG
Dr Tawfique Daneshmend	Consultant Gastroenterologist & Hepatologist	RD&E NHS Foundation Trust
Paul Foster	Chief Pharmacist	SDHC NHS Foundation Trust
Dr Keith Gillespie*	GP Clinical Commissioner	NEW Devon CCG
Dr Andrew Gunatilleke	Consultant in Pain Management & Anaesthesia	SDHC NHS Foundation Trust
Dr Steven Hunt*	GP Clinical Commissioner	NEW Devon CCG
Dr Phil Melluish*	GP Clinical Commissioner	South Devon & Torbay CCG
Mac Merrett	Lay Member	
Tracey Polak	Assistant Director/Consultant of Public Health	Devon County Council
Chris Roome	Head of Clinical Effectiveness	NEW Devon CCG
Dr Alison Round*	GP Clinical Commissioner	NEW Devon CCG

Guests:

Dr Daniel Flanagan	Consultant Physician	Plymouth Hospitals Trust
Petrina Trueman	Joint Formularies Pharmacist	NEW Devon CCG
Sanjay Verma	Clinical Evidence Pharmacist	NEW Devon CCG

In attendance:

Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NEW Devon CCG
Rebecca Heayn	Clinical Effectiveness Governance Manager	NEW Devon CCG

* Denotes voting members

1. Welcome and introductions

Attendees were welcomed to the meeting and the group introduced themselves.
Dr Darunee Whiting had delegated voting authority to Richard Croker for this meeting.

1.1 Apologies

Darunee Whiting	GP Clinical Commissioner	NEW Devon CCG
Sue Baldwin	Lead Designated Nurse for Safeguarding Children	NEW Devon CCG

1.2 Confirmation of voting members and Declarations of Interests

The eight voting members present were noted.

Declaration of Interest Forms were collected. The Chair informed the committee that declarations of interest had been made by the diabetes specialist present. The committee requested that clarification be sought as to which company was referred to in the declaration. Details of declared interests will be recorded in the minutes.

DRUG/TECHNOLOGY TO BE CONSIDERED	PHARMACEUTICAL COMPANY / MANUFACTURER / SERVICE PROVIDER
Imiquimod 3.75% (Zyclara®) **Imiquimod 5%** (Aldara®) **Diclofenac 3%** (Solaraze®) **5-fluorouracil/5-FU 5%** (Efudix®) **methyl aminolevulinate** (Metvix®)	**Meda Pharmaceuticals** **Meda Pharmaceuticals** **Almirall Limited** **Meda Pharmaceuticals** **Galderma (U.K) Ltd**
Survimed OPH HN® **Perative®**	**Fresenius-Kabi** **Abbott Nutrition**
Insulin Degludec (Tresiba®) **Insulin glargine** (Lantus®) Insulin pump manufacturers (various)	**Novo Nordisk** **Sanofi-Aventis**

NAME OF ATTENDEE	ROLE	
Dr Daniel Flanagan	Consultant Physician	In receipt of payment/gift for transport and hospitality to attend national or international meetings or symposia. Travel and accommodation for European association for the study of diabetes meeting September 2012 from Novo Nordisk

1.3 Notification of any other business

The chair asked the committee if there were any items to be discussed under AOB.

2. Minutes of the meeting held on 4th September 2013 and matters/actions arising

The minutes from the meeting held on 4th September 2013 were approved.

Actions from previous meeting:

13/20 *Options appraisal for declaration of interests to be brought to future meeting*

Declaration and handling of potential conflict of interest had been included on the meeting agenda.

Action complete.

13/28 *Appeals procedure to be considered and report brought to future CPC meeting*

Item to be included on the agenda for the CPC meeting due to take place in November 2013.

13/29 *Abatacept commissioning policy to be published*

Action compete.

13/30 *Rituximab with methotrexate commissioning policy to be published.*

Action complete.

13/31 *Tocilizumab without methotrexate commissioning policy to be published*

Action complete.

13/32 *Rituximab without methotrexate commissioning policy to be published*

Action complete.

13/33 *DAS scores for initiation of biologics for rheumatoid arthritis commissioning policy to be published*

Action complete.

13/34 *Multiple chemical sensitivity policy to be removed from NEW Devon CCG website*

Action complete.

3. Declaration and handling of potential conflict of interest

The committee received an options appraisal for handling declarations and potential conflicts of interests. Recommendations had been made following consideration of the literature including that produced by the NHS Confederation, the Constitutions of NEW Devon CCG and South Devon and Torbay CCG, the Seven Principles of Public Life set out by the Committee on Standards in Public Life (the Nolan Principles) and the National Prescribing Centre principles and rationale for local decision making. The committee were asked to consider:

- conflicts and declaration of interests in relation to members of decision making groups
- declarations of interest of guests in attendance for discussion and consideration of specific items

The committee discussed a number of issues pertinent to declarations of interest and conflict handling including:

- the methods and extent of the influence of pharmaceutical companies on consultants/clinical departments/GPs.
- the involvement of specialists in pharmaceutical development and the influence they can have on commissioning decisions was considered. It was suggested that specialists leave the meeting before a decision is taken, however the benefits of specialists being able to clarify any queries during the discussion prior to a decision being made would be lost. Their presence adds to the transparency of the decision making process.
- how GP voting members should respond to drug reps. It was suggested that members declare any meetings with drug reps.
- that declaration of interest forms are accepted in good faith however details cannot be checked.
- the committee accepted the recommendations in the paper. It was also suggested that the form be amended to include space for GP voting members to record details of drug reps they have seen since their last attendance.

ACTION: Declaration of Interest Form to be amended to include space for voting members to record details of drug company rep contact.

4. Committee members development session – Evidence Assessment

It had been agreed that a programme of development would be produced for committee members. The first session has been scheduled as part of the next CPC meeting, this will include a presentation and consideration of the information included in meeting papers. Future sessions will be organised around specific themes.

5. Intrathecal baclofen for severe spasticity in adults

As part of the work being undertaken to align commissioning policies across Devon consideration had been given to intrathecal baclofen pump for severe spasticity in adults. Hilary Pearce – Clinical Effectiveness Pharmacist, NEW Devon CCG had written a paper.

NHS Devon Effective Practice Committee approved a commissioning policy for intrathecal baclofen for severe spasticity in adults in September 2011. Torbay Care Trust Healthcare Funding Request Group adopted the NHS Devon Policy in January 2012. NHS Plymouth did not have a commissioning policy for intrathecal baclofen pump.

NHS England have issued a clinical commissioning policy for intrathecal baclofen supporting intrathecal baclofen for patient groups for which it is most cost effective, where other options are exhausted, and where patient and carer evidence shows a real likelihood of success.

The NHS Devon policy and the Torbay Care Trust policy are no longer valid and have been removed from the website. The NEW Devon CCG website has been updated to indicate that the commissioning of intrathecal baclofen is the responsibility of NHS England.

6. Urinary catheterisation

As part of the work being undertaken to align commissioning policies across Devon consideration had been given to urinary catheterisation. Hilary Pearce – Clinical Effectiveness Pharmacist, NEW Devon CCG had written a paper.

NHS Plymouth policy ratification group ratified a policy in June 2011 at a time when NHS Plymouth was a commissioning and provider organisation. NHS Plymouth continence service became part of Plymouth Community Healthcare CIC. The policy was updated in June 2013 and is available via the Plymouth Community Healthcare website and Plymouth Healthnet.

The document has been removed from the list of policies which fall under the policy variation workstream. No further action is required.

7. Imiquimod 3.75% (Zyclara) For Actinic Keratosis

An application had been received requesting the inclusion of Imiquimod 3.75% (Zyclara) onto local formularies.

The committee were asked to consider the evidence for commissioning Imiquimod 3.75% (Zyclara™) for Actinic Keratosis (AK). Sanjay Verma, Clinical Evidence Pharmacist, NEW Devon CCG presented an evidence review.

AKs are keratotic lesions found on skin chronically exposed to sunlight. Zyclara™ is licensed for the topical treatment of clinically typical, non hyperkeratotic, non hypertrophic, visible or palpable AK of the full face or balding scalp in immunocompetent adults when other topical treatment options are contraindicated or less appropriate. It is available in sachets, each containing 9.375 mg of imiquimod in 250 mg cream (3.75%). Zyclara should be applied once daily before bedtime to the skin of the affected treatment field for two treatment cycles of 2 weeks each separated by a 2-week no-treatment cycle. The cream should remain on the skin for approximately 8 hours.

The committee reviewed the evidence for Zylcara™ for AK. The evidence came from a study conducted by Swanson et al (2010) which investigated two identical placebo controlled trials, the results of which had been pooled together for analysis. The trials were randomised, multicentre, placebo-controlled studies. Efficacy was assessed at 8 weeks post-treatment. The primary efficacy endpoint was the complete clearance rate, defined as the proportion of patients at the end of study visit with a count of zero lesions in the treatment area. Within each study, Zyclara™ was demonstrated to be superior to placebo with respect to complete clearance rates, partial clearance rates, and percentage reduction in AK lesions from baseline. Treatment related adverse events were lower with placebo than with Zyclara™. Similarly, there was a greater incidence of patients experiencing local skin reactions with Zyclara™ than placebo. Sustained clearance was observed in 40.5% of the patients who were lesion free at the end of the initial 8 week follow-up. No head-to-head trials have been performed, however studies have shown other treatments exhibiting higher complete clearance rates relative to placebo.

Zyclara™ is costlier than other treatment options (except PDT/Metvix™) when treating an area of 25 cm^2 but can be cheaper than other therapies when treating larger areas (£113 for 100cm^2 and £226 for 200 cm^2) even after including the costs of treatment failures who can receive 2nd line treatments.

The committee discussed a range of issues pertinent to this therapy:

- the lack of head to head and long term trial data was noted. All the trials had been against placebo rather than products available;
- cost effectiveness - including potential wastage;
- concerns over patient compliance with treatment regimen and the achievement of clearance rates seen in the trials;
- other current treatment options including those given in primary care and photodynamic therapy given in secondary care;

- the potential impact of commissioning the therapy may be to reduce hospitals' income however capacity may be freed up. Currently there are insufficient trained dermatologists and trusts are finding it difficult to meet targets and undertake follow-up;
- commissioning options - Zyclara™ could be added to the formulary with the intention that Formulary Interface Groups decide its place in therapy which is likely to be hospital use only. However if Zyclara™ is not routinely commissioned the only commissioner funded route would be through the Individual Treatment Panel. Individual off formulary treatments might occur locally where the hospital bears the cost.

The committee voted unanimously against commissioning Imiquimod 3.75% (Zyclara™) for Actinic Keratosis.

ACTION: Commissioning policy to be published.

8. Survimed OPD HN 500ml

An application has been received requesting the inclusion of Survimed OPD HN in the formulary, to be used in place of Perative, where such formularies include a section on tube feed products. The application arose due to purchasing contract changes.

Petrina Trueman, Joint Formularies Pharmacist, NEW Devon CCG, informed the committee that survimed OPD HN is a nutritionally complete, peptide based liquid tube feed, with a high nitrogen content supplied ready to use in a 500ml EasyBag. It is classified as a Food for Special Medical Purposes and is intended for the dietary management of patients with malabsorption. It may be prescribed in primary care. The usual dose to provide complete nutrition is 1000-1,500mls daily.

No data exists comparing the use of Survimed OPD HN to Perative. The products have a similar nutritional composition and likewise any adverse events are expected to be similar.

NICE CG32 identifies that nutritional support should be considered in the acute and community settings for patients who are malnourished or at risk of becoming malnourished including for patients who may have poor absorptive capacity. In the acute trusts, all Fresenius products are charged at the nominal cost of one penny per pack. This contract is due to expire in 2014. Within the acute trust setting, there is a cost saving of £364 per patient per month using Survimed OPD HN in place of Perative, based upon a daily dose of 1,000mls. In primary care the difference will be minimal since the difference in unit cost (per 500ml) between the two products is minimal.

The Clinical Policy Committee considered what should be the CCGs' policy on accepting and deleting items into routine use through the formulary where the considerations are principally of a 'technical nature'. This would include issues such as contract changes, product discontinuations or availability problems, the entry of generic products, changes in formulations etc. It concluded that it would be disproportionate and unnecessarily bureaucratic for formulary commissioning policy to be considered through the CPC. The Formulary Interface Groups (FIGs) should agree such amendments locally. Deletions from the formulary which would cause a tension with NICE guidance, existing CPC policy, NHS England policies or result in inequity of access across Devon to specific pharmacologically active therapies should be referred to the CPC.

The list of technical changes is not exhaustive and it is left to the discretion of the formulary team and the Head of Clinical Effectiveness to determine, in the first instance, whether the proposed change is a technical change or is one with wider policy relevance.

The position of the clinical policy committee is that where a product contains the same active ingredient and delivers a therapeutically equivalent dosage to an existing formulary product in a cost advantageous manner the formulary team should make proposals to the FIGs directly about inclusion or exclusion of the product.

It was agreed that this position should be formalised in the governance arrangements for the CPC. A proposed formalisation of wording and proposal to include this in the governance documents of the CPC would be e-mailed to members.

ACTION: Proposed formalisation of wording and proposal to include this in CPC governance documents to be e-mailed to members.

ACTION: Position to be formalised in the governance arrangement for the CPC.

9. Update from NICE Planning, Quality and Assurance Group (NPAG)

A meeting had taken place on Tuesday 3rd September. The main item to be reported was on the commissioning position of aflibercept. This was to be considered under item 12.

10. Future meeting dates and venues

Dates for meetings until September 2014 had been set and circulated to the group. Meetings had taken place at County Hall, Exeter, The Watermark, Ivybridge and Tiverton Hospital, members were asked to consider venue preferences.

11. Insulin Degludec for use in type 1 and type 2 diabetes

An application had been received requesting the inclusion of insulin degludec in local formularies. Petrina Trueman, Joint Formularies Pharmacist, NEW Devon CCG presented an evidence review. Dr Daniel Flanagan, Consultant Physician was present via teleconference for this item. It was confirmed that the company referred to on Dr Flanagan's Declaration of Interest for was Novo Nordisk. The Chair explained the process to the guest consultant and identified other committee members present.

The committee were asked to consider evidence for commissioning Insulin Degludec (Tresiba®) for use in two specific therapeutic areas:

- Type 1 diabetes (T1DM) patients with a history of problematic recurrent hypoglycaemic events who might otherwise be considered for an insulin pump.
- Type 2 diabetes (T2DM) patients with high insulin resistance who require in excess of 100 units per dose (Specifically the 200units/ml Flex-touch pen):
  - To avoid the need for multiple injections per dose through use of 200 units/ml pre-filled pen.
  - As an alternative to Humulin R 500 (unlicensed in UK) currently used in a small group of highly insulin resistant patients.

This new ultra-long-acting basal insulin licensed for treating T1DM and T2DM is given once-daily preferably at the same time; at least 8 hours should pass between doses. It is available in penfill cartridges and pre-filled pens, available in 100 units/mL and 200 units/mL variants. The dose required is dialled in units but the dose steps differ between the two strengths of degludec:

- 100 units/ml: 1 to 80 units per injection, in steps of 1 unit
- 200 units/ml: 2 to 160 units per injection, in steps of 2 units

The committee reviewed the evidence for commissioning IDeg for use in T1DM and T2DM diabetes. Trials involving IDeg include comparative studies with long-acting insulin analogues (detemir and glargine) and one trial involving sitagliptin. The primary objective was to confirm the efficacy of IDeg by demonstrating non-inferiority to comparator in change in HbA1c. Incidence of hypoglycaemia was assessed as a secondary endpoint along with a range of other measures. IDeg was demonstrated

as an effective insulin with glycaemic control targets similar to conventional treatments in T1DM and T2DM.

NICE TA151 recommends continuous subcutaneous insulin infusion (CSII) or 'insulin pump' therapy as an option for adults and children 12 years and older with T1DM. The application identified poorly controlled T1DM patients with recurrent hypoglycaemia problems as potentially benefitting from IDeg. A limitation of the evidence on T1DM is that patients with a history of recurrent hypoglycaemic episodes were excluded. No trials are available comparing the effectiveness of IDeg with CSII therapy. Studies found no difference in rates of overall hypoglycaemia compared to Glargine and a modest but statistically significantly lower rate of nocturnal hypoglycaemia (1 study).

With respect to T2DM patients, Dr Flanagan had identified IDeg 200units/ml as an option for highly insulin-resistant patients which reduced the number of injections required. Evidence relating to patients requiring large doses using 200units/ml IDec is limited to one study. No data are available comparing the effectiveness of 500units/ml insulin, currently used in a small number of patients, with IDec. The formulation of IDeg imposes a maximum dose per individual injection of 160 units. IDeg is the only licensed insulin available which is presented in a strength of 200u/ml. Education of patients and healthcare professionals who handle insulins and treat diabetes will be necessary to reduce the risk of dosing errors

The Scottish Medicines Consortium cost effectiveness assessment was considered. It was noted that this was primarily intended to assess the cost effectiveness of IDeg compared to insulin glargine for general use in type 1 and type 2 diabetes. The analysis was useful to inform the debate as it demonstrated the variability in the cost effectiveness estimates for IDeg, depending upon assumptions made.

The committee discussed a number of issues pertinent to this therapy:

- Clinical meaningfulness of the reduction in rate of nocturnal hypoglycaemia;
- Lack of data in patients who have problematic hypoglycaemia;
- Potential for reduced costs compared to insulin pump therapy but not clear if the treatment would be as effective;
- Potential for confusion of dosing ;
- Balance of the known increased cost against possibly very small advantages in type 2 diabetes;
- Degludec provides a licensed alternative to Humulin R500 currently used in some patients;
- Place in therapy - initiation of the drug would probably only be appropriate in secondary care, primarily for patients experiencing recurrent hypoglycaemic events. Not commissioning a therapy does not mean that it cannot ever be used. Given the high acquisitions costs of degludec it is unlikely that a trust would provide funding but would apply for exceptional funding instead.

The committee voted unanimously against commissioning IDeg for use in T1DM and T2DM.

ACTION: Commissioning policy to be published.

12. Revocation of existing policy on aflibercept for the treatment of Wet Age Related Macular Degeneration in patients with a suboptimal response to treatment with ranibizumab (Tabled paper)

The committee received a paper ‘Revocation of existing policy on aflibercept for the treatment of Wet Age Related Macular Degeneration in patients with a suboptimal response to treatment with ranibizumab’.

Ophthalmologists have previously expressed a desire to use aflibercept in patients who were not responding well to ranibizumab. The Peninsula Health Technology Commissioning Group

considered the evidence and issued a policy that aflibercept was not commissioned to patients with a sub-optimal response to ranibizumab or bevacizumab for the treatment of neovascular (wet) age-related macular degeneration and are treated in accordance with NICE TA155.

NICE TA294 "Aflibercept solution for injection for treating wet age-related macular degeneration" issued on July 24th 2013 states that Aflibercept solution for injection is recommended as an option for treating wet age-related macular degeneration only if:

- it is used in accordance with the recommendations for ranibizumab in NICE technology appraisal guidance 155 (re-issued in May 2012) **and**
- the manufacturer provides aflibercept solution for injection with the discount agreed in the patient access scheme.

Following publication of this guidance ophthalmologists have reiterated a desire to use aflibercept; including as a first line treatment for patients with wet AMD. The guidance makes no specific mention of whether aflibercept is restricted to first line treatment or whether the guidance extends to patients not responding well to ranibizumab. Clarification has been sought from NICE, the response indicated that both aflibercept and ranibizumab are recommended as options for the treatment of AMD and that the clinician should decide which of the drugs is appropriate for their patient, irrespective of previous treatment. The 90 day time limit for implementing NICE TA294 expires on October 22nd 2013.

The committee discussed issues pertinent to NICE TA294. The committee noted with regret that NICE did not consider any evidence related to second line use. However, the response from NICE would appear to leave the CCG little option but to remove the policy not to commission aflibercept in this scenario. Decision to be communicated by letter to Medical Directors and members of CPC distribution list. It was agreed that this issue would be reported directly to the Board of South Devon and Torbay Clinical Commissioning Group and to the Board of Northern, Eastern and Western Devon Clinical Commissioning Group.

One practice had undertaken an audit which had shown the potential for a considerable financial impact relating to TA294.

ACTION: Decision to be communicated by letter to Medical Directors and members of CPC distribution list.

ACTION: Issue to be reported directly to the Board of South Devon and Torbay Clinical Commissioning Group and to the Board of Northern, Eastern and Western Devon Clinical Commissioning Group.

13. Any Other Business

No other business was discussed.

Meeting closed at 12.45 pm

Summary of actions		
	Action	**Lead**
13/28	Appeals procedure to be considered and report brought to November meeting	Chris Roome/ Jo Roberts
13/35	Declaration of Interest Form to be amended to include space for voting members to record details of drug company rep contact.	Rebecca Heayn
13/36	Imiquimod 3.75% (Zyclara) for Actinic Keratosis commissioning policy to be published.	Rebecca Heayn
13/37	Proposed formal wording for accepting and deleting items into routine use to be e-mailed to members.	Fiona Dyroff
13/38	Policy on accepting and deleting items into routine use to be formalised in the governance arrangement for the CPC	Rebecca Heayn
13/39	Insulin Degludec for use in type 1 and type 2 diabetes commissioning policy to be published.	Rebecca Heayn
13/40	Decision on revocation of existing policy on aflibercept for treatment of Wet Age Related Macular Degeneration to be communicated to Medical Directors and members of CPC distribution list.	Rebecca Heayn
13/41	Revocation of existing policy on aflibercept for the treatment of Wet Age Related Macular Degeneration in patients with a suboptimal response to treatment with ranibizumab to be reported to CCG Boards.	Jo Roberts - SD&T Ali Round -NEW Devon CCG